510(k) Summary for the
Quantel Medical SOLUTIS

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

AUG 0 2 2013

Submitter:

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Summary Preparation Date: July 18, 2013

2. Names

Device Trade Name: SOLUTIS

Common Name: Ophthalmic Laser

Classification Names: Laser Instrument, Surgical, Powered and Laser, Ophthalmic
Product Code: GEX (21 CFR 878.4810) and HQF (21 CFR 886.4390)
Panel: General & Plastic Surgery and Ophthalmology

3. Predicate Devices

- Lumenis Selecta Duet (K021550)
- Lumenis Family of Ophthalmic laser Systems, Model : Selecta SLT (K081704)

4. Device Description

SOLUTIS is a Q-switched, frequency doubled Nd:YAG laser providing a wavelength of 532 nm for use in Selective Laser Trabeculoplasty. The treatment beam delivers a 4ns, 0.2-2 mJ adjustable single pulse of energy. The aiming beam and treatment beams are coaxial with each other and focused by the slit lamp objective to a 400µm spot at the focal point of the lens. The SOLUTIS is compatible with Haag Streit 900 BM and Haag Streit 900 BQ slit lamps only.

5. Indications for Use

The SOLUTIS Laser is indicated for use in:

- Selective Laser Trabeculoplasty (SLT)

6. Substantial Equivalence

The SOLUTIS Laser shares the same intended use and technological characteristics as the predicate devices, the Lumenis Selecta Duet (K021550) and the Lumenis Family of Ophthalmic Laser Systems, Model SELECTA SLT (K081704) and therefore is substantially equivalent to the predicate devices. The SOLUTIS and the predicate devices are Q-switched, frequency doubled Nd:YAG laser systems providing a wavelength of 532 nm. The maximum energy, repetition rate, pulse duration and other key technological characteristics are identical between the SOLUTIS and the predicate devices. No new questions of safety or effectiveness are raised. Therefore, the SOLUTIS is substantially equivalent to the predicate devices.

7. Performance Data

Laboratory testing was conducted to validate and verify that the SOLUTIS Laser met all design specifications and was substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

Quantel Medical
% Ms. Maureen O'Connell
President/Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K130933
Trade/Device Name: SOLUTIS
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: June 28, 2013
Received: July 05, 2013

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130933

Device Name: SOLUTIS

Indications for Use:

Selective Laser Trabeculoplasty (SLT)

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K130933